Virtual Reality as a Measure to Reduce Stress of Night-Shift Anesthesiologists: Study Protocol for a Cross-Over Design Trial

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Study protocol

Keywords: Virtual reality, anesthesiologists, stress, work overload, night shift

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Abstract

Background: Because of the severe deficiency of global anesthesia workforce, anesthesiologists are forced to face work overload and more night shifts, which can disturbe the biological rhythm and cause major stress and depression, causing negative even devastating outcomes for both themselves and the patients eventually. Virtual reality (VR) as a new measure to reduce stress and pain for patients, has been widely used in biomedical fields.The purpose of the study is to evaluate the potential effectiveness of VR technology in reducing the stress of night-shift anesthesiologists.

Methods: In this randomized controlled, cross-over design, single-center clinical trial, a total of 30 anesthesiologists are enrolled and randomized in a 1:1 allocation to either the VR immersion group (intervention group) or the routine night-shift group (control group) with a washout of 1 week. Anesthesiologists in the intervention group undergo VR immersion for twice while anesthesiologists in the control group will not watch VR videos during the night shift. The primary outcome is the difference between two groups about the score of NASA-TLX scale. Secondary outcomes include the score of CPSS, VAS and *MFI-20* scales, satisfaction degree of the participants, heart rate (HR), blood pressure (BP), the incidence of arrhythmia as well as incidence of chest tightness, headache, palpitations.

Discussion: It is unknown whether the use of VR technology during the night shift can reduce the stress of night-shift anesthesiologists. With the widely use of VR technology, a positive result of the trial could spur the hospital to apply the technology to reduce the stress of night shift doctors in every department as well as offer a relatively relaxed working environment.

Trial registration: ChiCTR2000031025 on March 21, 2020.

Background

More than 300 million people need to undergo surgery each year all over the world[1], and over 70% of them got no access to safe, affordable anesthesia or surgical care[2], and the severe deficiency of global anesthesia workforce was one of the causes of this phenomenon[3]. The lack of first-line doctors also led to work overload and more night shifts, which disturbed the biological rhythm and caused major stress and depression[4-7]. Exposed to long working hours, work overload, chronic sleep deprivation, need for sustained vigilance, continuous noise pollution and even the patients' halitosis[8], and contamination risk of COVID-19[9], anesthesiologists are forced to bear huge job stress[10-13], which further cause anxiety, depression, sleep disturbances, memory and attention disturbance, nightmare, need for medication and so on[14, 15]. Lindfors et al[16], found that about 68% of the Finnish anesthesiologists felt stress at work, and the proportion increased to 79% in Ireland[17]. It is reported that the anesthesiologists are suffering higher anxiety and stress, compared with other occupations[18]. It would also lead to negative even devastating outcomes for the patients if the anesthesiologists were under high stress for a long time. Therefore, an intervention that could reduce the stress of night-shift anesthesiologists could prove to be valuable in raising medical safety and protecting the health of the anesthesiologists.

Nowadays, virtual reality (VR) has been widely used in biomedical fields. It can alter our sense of personal presence to that of being in a virtual world, therefore the features of sensory and affective experience can be changed[19]. The new technology has been applied in hospitals to create an immersive environment to minimizes stress for both the doctors and patients. For instance, VR has been widely used before surgery to reduce preoperative anxiety in patients[20, 21]. What is more, the broad reach of VR has enabled its use for treating pain management, psychological stress, social and generalized anxiety disorders, depression, posttraumatic stress disorder (PTSD), as well as poststroke rehabilitation[22-24]. However, few studies have focus on the application of VR technology in the stress of night-shift anesthesiologists. Therefore, we conducted this study to evaluate the potential effectiveness of VR technology in reducing the stress of night-shift anesthesiologists.

Methods/design

Study design

The Virtual Reality immersion in the night-shift anesthesiologists trial is a randomized controlled, single-center clinical trial, using a cross-over design with a washout of 1 week. Anesthesiologists will be randomized in a 1:1 allocation to either undergo immersion relaxation using VR or not. Anesthesiologists undergo VR intervention undergo immersion relaxation via VR for twice in the night shift, the first one at 23:30 and the second one at 07:30 of the next day. They can choose the content of VR and enjoy themselves for 20 minutes. Anesthesiologists in the control group do not watch VR videos during the night shift. The design of the study is represented in **Fig. 1**.

The primary outcome of this study is the NASA Task Load Index (NASA-TLX) between the groups. Secondary outcomes include the score of CPSS, VAS and *MFI-20* scales, satisfaction degree of the participants, heart rate (HR), blood pressure (BP), the incidence of arrhythmia as well as incidence of chest tightness, headache, palpitations.

Setting

The study is conducted in the Third Affiliated Hospital of Sun Yat-sen University, a large comprehensive hospital in Guangzhou, China. The hospital is a tertiary medical facility which serves as a teaching hospital for Sun Yat-sen University.

Study registration

The study protocol is in accordance with the principles of the Declaration of Helsinki, approved by the Institutional Review Board (IRB) of the hospital (approval number:[2020] 02-021-01), and registered with the Chinese Clinical Trial Registry at www.chictr.org on March 21, 2020 (registration no. ChiCTR2000031025). The trial is currently active and ongoing, and any amendments of the protocol can be reported to and approved by the IRB.

Inclusion and exclusion criteria

To be eligible, participants must meet all of the following inclusion criteria: 1) Participants who work for the hospital; 2) Aged 25–45 years (either sex); 3) The American Society of Anesthesiologists (ASA) of patients they are managing are I to II; 4) Each operation takes 2 to 4 hours. The exclusion criteria included: 1) Participants who refuse to sign the informed consent; 2) With serious cardiopulmonary diseases; 3) Other researchers determine that the patient is no longer eligible to participate the study.

Randomization

Following informed consent, participants are randomized in a 1:1 allocation using block randomization of equal size to either VR immersion group (intervention group) or the routine night-shift group (control group). The allocation do not be informed to researchers who is going to conduct the trial until the participant is enrolled and assigned. Besides, the researchers who perform the statistical analyses are blinded to the group allocation.

Drop-out criteria

The informed consent is obtained before the trial. The participants can voluntarily withdraw from the study whenever, although they had been provided informed consent.

Intervention group: virtual reality immersive relaxation

Participants in the VR immersion group (intervention group) are asked to wear the VR headset and choose the kinds of videos based on their preferences to relax themselves in the rest room. They are asked to watch videos for twenty minutes at 23:30 and at 07:30 of the next day. They need to finish the NASA-TLX scale, CPSS, VAS and *MFI-20* scale before and after watching the videos. When the participants are watching the videos, anesthesiologists with the same qualifications will take over their work until they finish the VR immersion.

Control group: the routine night-shift group

Participants in the control group undergo a routine night shift without the VR immersion experience.

Data collection

The participants' general characteristics including sex, age, body mass index (BMI), heart rate (HR), blood pressure (BP), electrocardiogram (ECG) are collected. In order to assess the effect of VR immersion in reducing the stress of night-shift anesthesiologists, a number of six time-points are set to collect the data of participants in intervention group, including 07:50, 17:30, 23:30; 23:50 on the day that they are undergoing night shift, and 07:30, 07:50 of the next day. Data of the control group are collected at 07:50, 17:30, 23:50 on the day that they are undergoing night shift and 07:50 of the next day. At each time-point, participants are asked to finish the NASA-TLX scale, CPSS, VAS and *MFI-20* scale. In addition, their ECG are also recorded using an artificial intelligence cardiologist (Anhui xinzhisheng Medical Technology Co., Ltd) at each time-point. Besides, the anesthesiologists are asked to record their ECG whenever they feel

discomfort during night shift. The incidence of arrhythmia, satisfaction degree, as well as incidence of chest distress, headache or heart palpitations are also recorded by the researchers. The data recording flow chart is presented in **Fig. 2**.

Reporting of compliance and adverse events

Anesthesiologists who had experienced something pleasant or sad during the week are excluded because of the potential influence on their emotion states. It was reported that young people are more vulnerable to suffer physical discomfort, such as seizures, severe dizziness, eye twitching, or blackouts triggered by light flashes, when they wearing the VR headset[25] so the anesthesiologists who can not bear the VR headset are excluded to mitigate these risks. If the participants experience any discomfort symptoms during the procedure, the trial can be stopped and the participants can be treated accordingly. In order to ensure the safety of patients, anesthesiologists with the same qualifications take over the participants' work when they are undergoing VR immersion.

Statistical analysis

Sample size calculation

Based on our preliminary data from the intervention group, the score of NASA-TLX (mean±SD) was 65.5±16.8 before intervention and was 55.7±18.2 after intervention. Using a two-sided α of 0.05, 80% power, an allowable error of 11, we anticipated a sample size of 27 participants are needed in each group. To account for a potential dropout rate of 10%, 30 participants will be enrolled.

Data analysis

The case with missing data was eliminated. Both quantitative and qualitative analysis methods will be used in the study. The Kolmogorov-Smirnov and Shapiro-Wilk tests are going to be used to test the normality of continuous data. The normally distributed data will be presented as mean±SD and analyzed by the Student t test. Non-normally distributed data will be expressed as median (interquartile range) and analyzed by the Mann-Whitney U test. All data analysis will be performed using SPSS for Windows V.16.0 (SPSS Inc., Chicago, Illinois, USA). In order to avoid bias, the data analyst is blind to the data.

Analysis of primary outcome

Our primary outcome, the score of NASA-TLX scale, will be compared using one-way analysis of variance and followed by the Bonferroni test as the post-hoc test for multiple comparisons. Differences are considered significant when a two-sided *P* value is less than 0.05.

Analysis of secondary outcomes

Secondary outcomes including sex, age, BMI will be expressed as presented as the mean±SD and median (interquartile range). Repeated measure of ANOVA will be used to detect the between-group differences on mean blood pressure (MBP) and heart rate (HR). Spearman's rank correlation test will be used to

analyze the association between work hours and the score of the scales. Qualitative/rank datas such as the incidence of arrhythmia, chest distress, headache as well as heart palpitations, and satisfaction degree are going to be presented as percentage/ composition ratio and analyzed by the Pearson χ^2 test or Fisher's exact test. The effect of VR immersion on the score of CPSS, VAS and *MFI-20* scales are going to be compared using one-way analysis of variance and followed by the Bonferroni test as the post-hoc test for multiple comparisons. Differences are considered significant when a two-sided *P* value is less than 0.05.

Discussion

This study will be the first one to evaluate the potential effectiveness of VR technology in reducing the stress of night-shift anesthesiologists. The overload work, long working hours, continuous noise pollution and so on[26-28], have caused some physical and mental problem among anesthesiologists, such as psychological distress、Burnout Syndrome (BOS)、memory and attention disturbance and so on [29-32]. It was reported that the mental fatigue had served as the principal factor for causing medical error among anesthesiologists[33], and their high proportion of suicides[34]. A study showed that the risk of medical accident increases exponentially with each hour when the doctor had worked for nine hours consecutively. What is worse, the impairment of psychomotor function may be equivalent to a blood alcohol concentration of 0.1% if the doctor at 24 hours of sustained wakefulness, and the concentration is higher than the legal limit for driving in most states in the USA[35]. It was also reported that the rate of burnout among anesthesiologists was 48%, higher than the all-physician among the specialties studied[36]. The burnout rate of Chinese anesthesiologists was 69% while their consultation rates were 73%[37]. It is an urgent necessity to take more measures to curb their psychological distress without increasing the number of anesthesiologists.

VR technology has been widely used in clinical practice, such as treating the mental illness, reducing preoperative anxiety in patients[20-24, 38]. Shah et al[39], found that stress was the primary target while depression was the secondary in the VR mood induction procedure study.The current study would be a positive result adding to the evidence that VR technology can be used as a effective measure to reduce the stress of night shift anesthesiologists. These results might be attributed to that watching VR videos could avoid long hours of night-shift work, distract the anesthesiologists and allow them to have a rest, and this would make them become positive and vibrant again.

However, there are still several limitations in the study. First, because of the connectivity issues of the VR technology, a non-immersive environment may arise, which possibly interfere with the participant relaxation and the subsequent satisfaction degree. Secondly, the study is susceptible to selection bias from the content of videos since we do not limit the kinds of videos. Some terrified videos or rock songs may influence relaxation. Thirdly, the study is a single-centre,cross-over designed with a small sample size. Therefore, it is better to confirm the preliminary results by a large-scale multicentre study.

Although the VR technology has been widely use in biomedical fields, it is still unknown whether the use of VR can reduce the stress of night-shift anesthesiologists during the night shift. A positive result of the trial could spur the hospital to apply the technology to reduce the stress of night shift doctors in every department, creating a relatively relaxed working environment where both the doctors and patients can get benefit.

Abbreviations

ASA: American Society of Anesthesiologists; BOS: Burnout Syndrome; BMI: body mass index; CPSS: Chinese Perceived Stress Scales; CRH: corticotropin releasing hormone; CRP: C-Reactive Protein; ECG: electrocardiogram; HR: heart rate; IRB: Institutional Review Board; MBP□mean blood pressure; *MFI-20:* Multidimensional Fatigue Inventory; NASA-TLX: NASA Task Load Index; PTSD□posttraumatic stress disorder; VAS: Visual Analogue Scale; VR: Virtual reality

Declarations

Acknowledgement

We would like to acknowledge the participants in our department for their support of this study.

Trial registration information

Registered with the Chinese Clinical Trial Registry at www.chictr.org on March 21, 2020 (registration no. ChiCTR2000031025).

Trial status

This is protocol version 1.0 (21, March, 2020). First recruitment date: 11

May, 2020. Approximate recruitment completion, 11 August 2020.

Authors' contributions

All authors have contributed to the conception or design, acquisition,

analysis, or interpretation of data or manuscript preparations for this study.

CJ-C, ZQ-H, QZ conceived the idea for this trial. CJ-C, LB-C, NS, CF-L drafted, reviewed and finalized the study protocol. RW and HY-F developed the statistical analysis plan. All authors have read and approved the final version of this manuscript. Only authors who were critically involved in the drafting and revision of this manuscript were considered for authorship. All authors have approved the final version of this manuscript. There is no intended use of any professional writers for this manuscript.

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Availability of data and materials

The data of this study are available on request from the corresponding authors.

Ethics approval and consent to participate

The study protocol is in accordance with the principles of the Declaration of Helsinki, approved by the Institutional Review Board (IRB) of the Third Affiliated Hospital of Sun Yat-sen University (approval number:[2020] 02-021-01). Written informed consent is obtained from all study participants by the research team members (Additional file 1).

Consent for publication

Participants will consent to having their data and results published anonymously, just as described in the informed consent form (Additional file 1).

Competing interests

All authors declare that they have no competing interests in the study.

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Figures

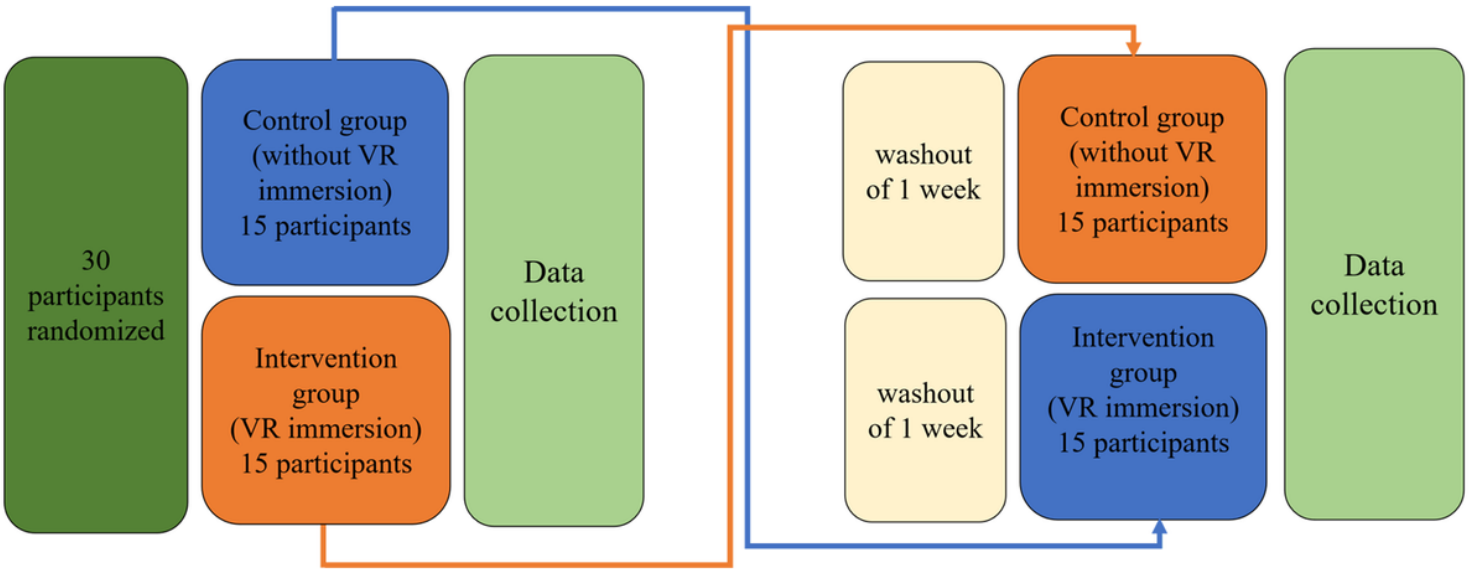

Figure 1

The cross-over design of the study.

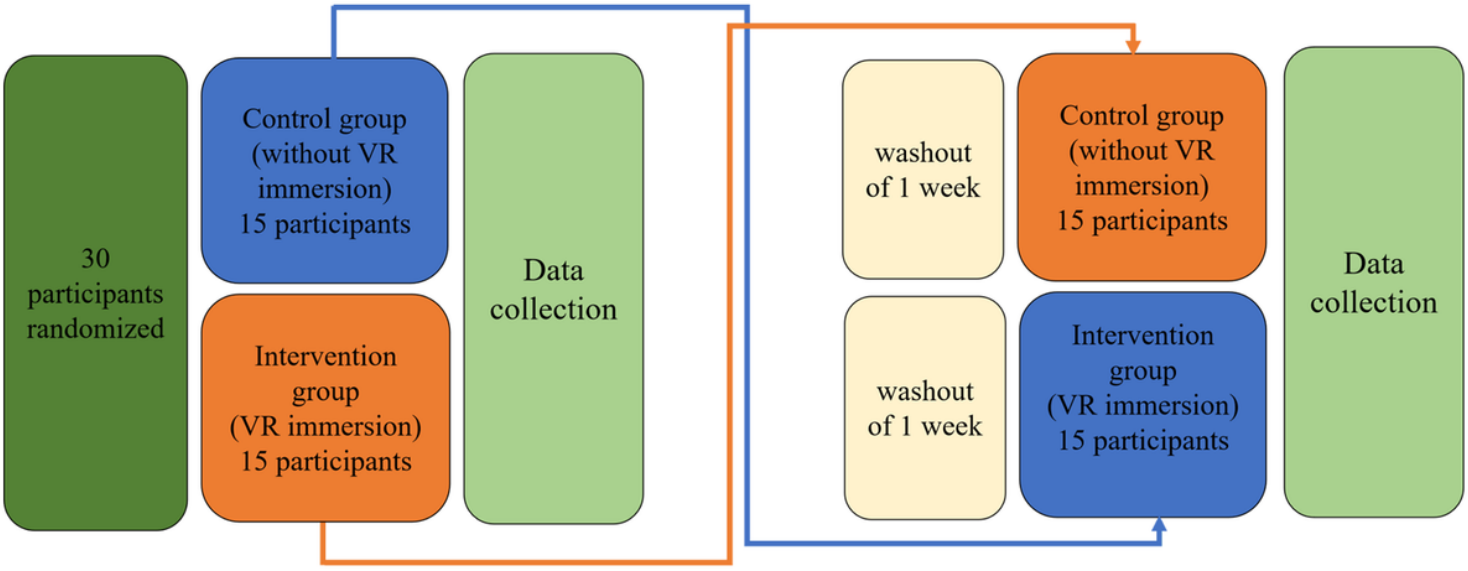

Figure 1

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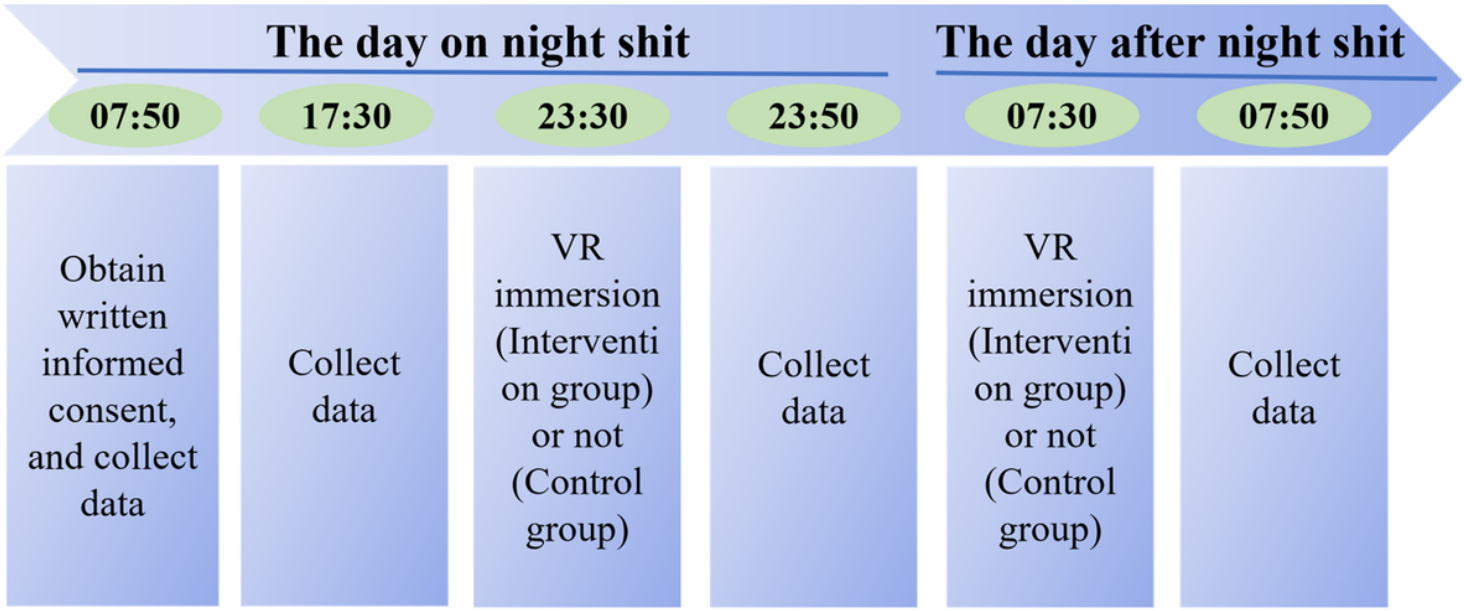

Figure 2

The data recording flow chart of the study.

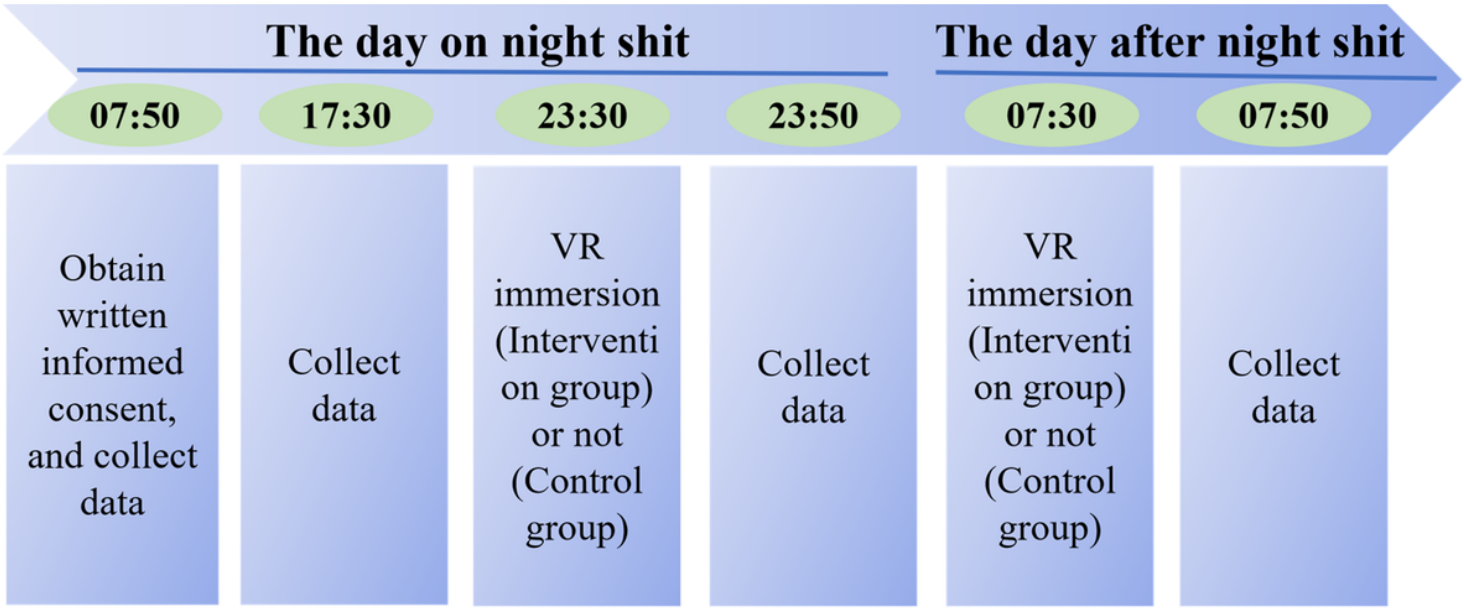

Figure 2

The data recording flow chart of the study.

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